II. RESPONSE TO THE OFFICE ACTION

A. Status of the Claims

Claims 26-51 are pending in the case. Claims 44-49 are withdrawn from consideration at the current time as being drawn to a non-elected invention. Claims 26, 33, 34, 36, 41, 42, 44-47, 50, and 51 have been amended to replace the recitation "80%" with "95%." Support for the amendment can be found in the specification at page 5, lines 15-18. Claim 35 has been amended to delete the term "substantially." Support for the amendment can be found at page 10, lines 13-16. No new matter was added by these amendments.

B. The Rejections Under 35 U.S.C. § 112, First Paragraph, Are Overcome

1. The Claims Are Supported by Adequate Written Description

Claims 26-28, 30-38, 40-43, and 50-51 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants traverse this rejection.

(a) Genus/Species

The Examiner asserts that the specification does not describe a representative number of species falling within the scope of the claimed genus. To support this assertion, the Examiner cites *Regents of the University of California v. Eli Lilly and Co.*, 119 F. 3d 1559 (Fed. Cir. 1997).

The Examiner appears to be misapplying the requirements of written description set forth in *Eli Lilly*, which requires only that claims to genetic material require recitation of more than a mere function. *Eli Lilly*, 119 F.3d 1559, 1568 ("In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function."). While it is true that in claims to genetic material, a generic

statement without more is not an adequate written description of the genus, the claims of the present application recite more than a mere function.

Current claim 26, for example, is directed to an isolated or purified nucleic acid comprising a plant promoter comprising a polynucleotide possessing at least 95% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof. This claim differs significantly from the claim at issue in *Eli Lilly.* In particular, current claim 26 provides a recitation of the structural features common to members of the genus. In other words, the members of the genus encompassed by claim 26 have the common structural feature of having at least 95% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof. Based on the fact that a person of ordinary skill in the art can understand that a nucleic acid sequence (*i.e.,* SEQ ID No. 1) provides the chemical structure needed to practice the invention, this information provides the recited structural information for every sequence that falls within the scope of the claim. Thus, Applicants are fully in compliance with the written description requirements set forth in *Eli Lilly.*

In addition, the *Interim Guidelines for the Examination of Patent Applications Under 35 U.S.C. 112, Paragraph 1* state that the "written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." Applicants are in compliance with the written description requirements set forth in the Guidelines.

Applicants further note that in the amendment filed with this response, claims 26, 33, 34, 36, 41, 42, 50, and 51 have been amended to recite "at least 95% nucleotide identity," thus narrowing the scope of the claims as compared to the previous recitation of "at least 80% nucleotide identity."

(b) Recombinant Host Cells, Plants, and Transgenic Plants

The Examiner states that the specification does not describe recombinant host cells, plants or transgenic plants comprising the polynucleotides or vectors of the present invention. Applicants would like to direct the Examiner's attention to the following locations in the specification where support can be found for recombinant host cells, recombinant host plant cells, and transgenic plants.

The specification describes a recombinant host cell characterized in that it contains a nucleic acid with plant promoter activity specific for plant roots according to the invention or a recombinant vector such as defined in the specification (Specification, p. 10, ln. 17-21). Preferred recombinant host cells according to the invention may be of bacterial or plant origin (Specification, p. 10, ln. 22-23). In particular embodiments, a recombinant bacterial host cell be a strain of *E. coli* or *Agrobacterium tumefaciens* (Specification, p. 10, ln. 24-25). A preferred recombinant host cell according to the invention is the cell of the *E. coli* strain deposited with NCCM on 25 May 1999 under the access No. I-2218 (Specification, p. 11, ln. 1-3).

The specification also discloses that recombinant plant host cells, such as cells of *Arabidopsis thaliana*, colza, tobacco or maize, may be transformed by a vector in conformity with the invention (Specification, p. 10, ln. 26-28). The specification further describes recombinant plants characterized in that they comprise recombinant host cells such as those described above (Specification, p. 11, ln. 4-6). In particular, the specification discloses a

transgenic plant comprising in a form integrated in its genome a nucleic acid according to the present invention (Specification, p. 11, ln. 7-11).

In view of the above, Applicants submit that the specification provides adequate written description for recombinant host cells, recombinant host plant cells, and transgenic plants.

(c) Claim 35

The Examiner asserts that the specification does not describe a vector substantially identical to a vector contained in an *E. coli* strain deposited with the NCCM under the access number 1-2218, or what aspect of the deposited vector would be characteristic of other vectors "substantially identical" thereto. Applicants have amended claim 35 to define the vector as being "identical" to the vector contained in an *E. coli* strain deposited with the NCCM under the access number 1-2218. Applicants, therefore, request the withdrawal of this rejection.

(d) Summary

For the reasons described above, the present specification provides adequate written description of the claimed invention. Applicants, therefore, request the reconsideration and withdrawal of this rejection.

2. The Claims Are Enabled

(a) Claims 35 and 39

Claims 35 and 39 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner states that the *E. coli* strain deposited with the CNCM under the access No. I-2218, and the vector contained therein, are required to practice the claimed invention. As such, they must be obtainable by a repeatable method set forth the in the specification, or otherwise be readily available to the public.

The *E. coli* strain, and the vector contained therein, are deposited in accordance with the Budapest Treaty. A copy of the filing deposit of the strain P Bin19-insert2 at the CNCM of the

Institut Pasteur on May 25, 1999 under the access number I-2218 is attached as Appendix A. The vector and cell will be made available to the public upon the issuance of a patent in accordance with 37 C.F.R. § 1.808.

In view of the above, Applicants request the withdrawal of this rejection.

(b) Claims 26-34, 36-38, 40-43, and 50-51

Claims 26-34, 36-38, 40-43, and 50-51 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner states that the specification, while being enabling for an isolated or purified nucleic acid comprising a plant promoter comprising the nucleotide sequence of SEQ ID No. 1, does not reasonably provide enablement for other promoter nucleotide sequences. Applicants traverse.

To be enabling within the meaning of 35 U.S.C. § 112, the application must contain a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984). A considerable amount of experimentation is permissible if it is routine, or if the specification in question provides a reasonable amount of guidance with respect to the experimentation. *In re Jackson*, 217 U.S.P.Q. 804, 807 (Bd. App. 1982).

The biological activity of a polynucleotide promoter according to the present invention can be easily verified by those skilled in the art (Specification, p. 5, ln. 29-30). The present specification provides reasonable guidance concerning the evaluation of a polynucleotide's promoter activity. For example, the promoter function of a polynucleotide can be assayed using the *gus* reporter gene (p. 24, ln. 26 – p. 25, ln. 6; p. 28, ln. 14 – p. 29, ln. 28). As indicated by the publications of Jefferson *et al.*, Bouchez *et al.*, and Mollier *et al.* cited in the specification, the *gus* gene is a routinely used reporter system in plants.

The specification also provides reasonable guidance concerning how to make various fragments of SEQ ID No. 1. For example, one skilled in the art could use the restriction map of SEQ ID No. 1, shown in FIG. 1, to select restriction enzymes for the purposes of obtaining polynucleotide fragments corresponding to a part of a polynucleotide promoter according to the invention; alternatively, a polynucleotide promoter according to the invention can also be prepared by specific amplification of the fragment of interest with the aid of a primer couple flanking the sequence of interest from the 5' side and the 3' side, respectively (p. 26, ln. 28 – p. 27, ln. 12). In addition, the exonuclease III method, which is described in the specification at page 21, line 17 to page 23, line 6, could be used to make deletions in SEQ ID No. 1. The specification also provides guidance on determining the "percentage nucleotide identity" between two sequences (p. 4, ln. 20 – p. 5, ln. 18). Polynucleotides made according to these or other methods could then be screened for promoter activity as described in the specification.

In addition, the specification provides guidance for determining whether two nucleic acid sequences hybridize under conditions of high stringency (p. 7, ln. 13 – p. 8, ln. 5). Moreover, nucleic acid hybridization is well-known and routine in the art as evidenced by the publications of Hames and Higgins, and Sambrook *et al.*, both of which are cited in the present specification.

Finally, Applicants note that in the amendment filed with this response, claims 26, 33, 34, 36, 41, 42, 50, and 51 have been amended to recite "at least 95% nucleotide identity," thus narrowing the scope of the claims as compared to the previous recitation of "at least 80% nucleotide identity."

In view of the above, Applicants submit that it would require only routine screening for one skilled in the art to make and use the invention commensurate with the scope of the claims. Applicants, therefore, request the reconsideration and withdrawal of this rejection.

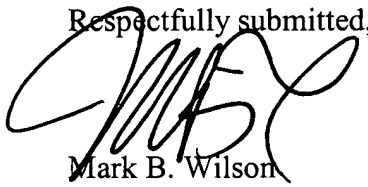
C. Conclusion

Applicants believe that this paper is a full response to the Office Action dated August 11, 2004, and respectfully request consideration of the instant claims in view of the remarks made above.

Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-3035.

Please date stamp and return the enclosed postcard evidencing receipt of this paper.

Respectfully submitted,



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